

REMARKS

Claims 1-17 and 21-23 were presented for examination and were variously rejected, and the rejection was made final. The grounds for rejection have been carefully considered, and the present amendment and remarks are offered in response. Reconsideration is respectfully requested.

Claim 1 is amended to modify a proviso; the amendment is supported by the specification as filed, e.g. at paragraph [0024]. The amendment adds no new matter. Entry of the amendment is respectfully requested.

Objections to the Claims

The Examiner objected to the claims because they allegedly contain non-elected subject matter. The claims are believed to correspond to the scope of the Group that was elected for examination, and this objection is understood to relate to claim scope the Examiner has challenged based on prior art and/or other grounds for limiting the scope of the search beyond the elected species. The applicant has provided further arguments that support patentability of this subject matter; therefore, the challenged subject matter has not been withdrawn or cancelled, because this subject matter should be further examined if the applicant overcomes those grounds for limiting the scope of the search. The applicant respectfully requests reconsideration of the objection in view of the amendments herein and the following comments.

Rejections based on 35 USC 103

Claims 1-17 were rejected as obvious in view of Kuroita, et al., U.S. Patent No. 6,468,998. The applicant pointed out in a previous response that the rejection did not appear to provide proper evidence of a motivation to select the claimed invention under the standards applied in In re Baird. The Examiner alleged that Baird is distinguishable from this case:

In the instant case, the claimed compounds are *not* more complex than those proposed by Kuroita. One species is particular, corresponds to claimed compounds where n is 0, W is L^2-A^3 , L^1 is $C(O)$, X^1 is CR^3 , L^2 is CH_2CH_2 , A^1 , A^2 , and A^3 are 4-fluorophenyl, and R^1 , R^2 and R^3 are hydrogen. See Example 67, column 30, lines 54-61, and the structure on column 33, lines 1-17. The only difference that is required to meet the scope of claim 1 is for the linking group to be extended or contracted, (L^2 in the instant case and D in Kuroita et al.) to overcome the new proviso... Since Kuroita et al. defines D to be:

D is optionally substituted linear or branched chain alkylene having 1 to 8 carbon atoms, and when D is branched alkylene, the carbon atoms in the branched chain is optionally bonded further to Ar to form 4- to 8-membered ring, and...

One of skill in the art would take the compound cited above, have motivation to use a different linking group between the para-fluorophenyl and the pyrrolidine nitrogen, and would have a reasonable expectation of success that the compounds will still antagonize 5-HT₂ to treat glaucoma and other ailments. See column 4, lines 38-43 and column 17, lines 51-63. Therefore, since only one group needs to be modified to take a disclosed species of Kuroita et al. to generate a compound of the instant claims, and that modification is sufficiently suggested within the reference, one of ordinary skill would have motivation to make the change to practice fully the invention of Kuroita et al. The rejection is maintained.

First, the Examiner's emphasis (see above) appears to suggest that In re Baird applies only where the claimed compounds are 'more complex' than those in the reference. That relates to the *facts* of Baird, but it does not represent the *rule* from Baird, which seems to lie in the conclusion of the sentence that states those facts: "we conclude that Knapp does not teach or fairly suggest the selection of bisphenol A." In re Baird, 29 USPQ2d 1550 (Fed. Cir. 1994). Thus the standard applied in Baird asked whether the reference 'teaches or fairly suggests' selection of what was claimed. See also the paragraph in Baird preceding that sentence: "While Knapp may suggest certain complex bisphenol A derivatives, it does not describe or suggest bisphenol A and therefore does not motivate the selection of bisphenol A." Id. (emphasis added). Thus Baird provides a standard for examination that requires the Examiner to show that the prior art "describes or suggests" the invention as claimed in order to establish a *prima facie* obviousness rejection, or that it "motivates the selection" of the invention as claimed. Simply stating that the reference discloses a particular species, which

could be modified in a certain way, is not enough to establish obviousness under Baird, unless the reference is also shown to provide a reason to make the required changes. And simply showing that the modification remains within the disclosed genus does not show a motivation to make such modification.

Here, the Examiner selected which feature of the prior art to modify from many possibilities, and the Examiner selected which modification to make from among many options. The reference discloses various features that could be modified and many ways to modify them, but has not been shown to provide any reason to select the changes required to arrive at the invention as claimed. (For example, the feature the Examiner chose to modify is D, and the specification says D is “optionally substituted linear or branched alkylene having 1 to 8 carbon atoms, and when D is branched alkylene, the carbon atom in the branched chain is optionally bonded further to Ar to form 4- to 8- membered ring, ...” Thus it provides many alternatives that could have been made, and the Examiner has not shown that a person of ordinary skill would have had reason to choose the particular one used in the analysis.) The Examiner’s approach implies that nothing more is required to establish obviousness than showing that a modified structure that could be made remains within the scope of the claims, contradicting one *clear* rule from Baird: a genus in the prior art does not render obvious all that it encompasses. Obviousness is established by showing motivation to modify, not by merely showing that modification could be done while remaining within the scope of the genus.

The Examiner has shown that *once the applicant’s invention is known*, it is possible to modify a species from the reference to fall within the scope of the broadest claim. That does not satisfy the burden placed on the Examiner by In re Baird to show that either the reference, or the general level of skill in the art, would have *suggested* to the person of ordinary skill to make the *particular selections and changes* needed to get there. And Baird clearly demonstrates that claimed subject matter is not ‘obvious’ simply because it falls within a disclosed genus, if the teachings of that genus do not “motivate the selection” of what is now claimed. Thus the Examiner has not established a *prima facie* obviousness rejection under Baird.

In addition, claim 1 has been amended. The Examiner alleged in the rejection that only one feature (D) of a compound disclosed in the Kuroita reference would need to be changed in order to avoid the proviso in claim 1. The Examiner then concluded, “since only one group needs to be modified to take a disclosed species of Kuroita et al to generate a compound of the instant claims, and that modification is sufficiently suggested within the reference, one of ordinary skill would have motivation to make the change to practice fully the invention of Kuroita et al.” The amended proviso excludes the modified versions proposed by the Examiner: modifying D (which corresponds to L² in the present claims) would not bring the compound of Kuroita within the scope of the claims, because the proviso no longer depends upon L². Thus the amendment overcomes the rationale for the rejection. As shown above, the Examiner has not shown motivation to make the proposed modification of the reference compound, and in view of the amendment, even making that modification would not provide a compound within the scope of the claims. Accordingly, this rejection can be withdrawn.

Claims 17 and 21-23 were alleged to be obvious based on In re Henze. The passage in Henze that the Examiner seems to rely on to support the rejection says this: “In effect, the nature of homologues and the close relationship the physical and chemical properties of one member of a series bears to *adjacent members* is such that a presumption of unpatentability arises against a claim directed to a composition of matter, the *adjacent homologue* of which is old in the art.” 85 USPQ 261 (1950) (emphases added). The Examiner stated that Henze refers to ‘adjacent members’ of a series when citing it, but then *applied* it as though it justifies rejecting any structure that can generally be characterized as a ‘homolog’. But, as shown above, Henze does not say that all homologues are *prima facie* obvious regardless of how different they are in structure, only that an adjacent homolog disclosed in the prior art may provide a *prima facie* basis for an obviousness rejection.

Nor does Henze show that homologs falling outside of a generally disclosed genus are a proper basis for an obviousness rejection: in Henze, “the adjacent homologue” was a specific compound that was disclosed and was thus “old in the prior art,” it was not merely included within a broad *genus* in the prior art. In this case, the genus as disclosed and described

in the prior art does not disclose or suggest *any* compounds that resemble the compounds of the claims; and the prior art genus does not even *encompass* such compounds. Rather, a prior art *genus* having a single atom linker was compared to a claim limitation requiring a 3-6 atom linker. The one-atom linker of the prior art genus is clearly not “the adjacent homologue” of a 3-6 atom linker as required by the claim.

The Examiner relied upon a genus in the reference to assert that effectively all ‘homologs’ of a non-overlapping genus are obvious: that reasoning cannot be squared with Baird, which expressly shows that a disclosed genus does not even render obvious all compounds that it encompasses. Describing a *genus*, without any sort of suggestion that anything outside the scope of the genus would be active, does not show that structures that are outside its scope, and cannot be properly characterized as ‘adjacent homologs’, are ‘obvious’. As one of ordinary skill would recognize, **the genus was deliberately drafted to exclude such compounds, implying that the drafter of the genus did not believe that other linkers would have the claimed activity.** Thus Henze does not support the conclusion that the claim limitation 3-6 is *prima facie* obvious over a 1-atom linker, and this rejection should be withdrawn.

Rejections based on 35 U.S.C. 112

The Examiner also maintained a rejection alleging that the claims lack written description. According to the Examiner, “The specification fails to teach compounds covering the entire scope of the claimed invention. For example, the depicted species in Figure 1 do not show any instances of a linking group carbon being replaced by N, O or S. Hence the working examples in the specification do not cover a representative number of compounds to cover the entire invention as claimed. Therefore, a person of skill in the art would deem that the Applicant did not possess the entire invention as claimed at the time of filing...”

The applicant respectfully traverses this rejection once again. First, two compounds wherein one of the linkers contains N in place of C are depicted as examples P16 and P45 in the

table. Second, while a claim may indeed be supported by a representative number of species (and this one is supported by numerous examples), there is no requirement that an invention must actually be reduced to practice before an application is filed, or that any examples must be presented: constructive reduction to practice, in the form of a patent application, is recognized as sufficient. Written description does not require *any* examples at all. Third, and most importantly, the language used by the Federal Circuit in discussing section 112 seems to precisely rebut the Examiner's basis for this rejection:

A claim will not be invalidated on section 112 grounds *simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language*. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724 (Fed. Cir. 2005) (citing Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227 (Fed. Cir. 2000) (emphasis added). *See also* Falkner v. Inglis, 79 USPQ2d 1001 (Fed. Cir. 2006).

Finally, the Federal Circuit has said that the description of a chemical genus using a generic structure satisfies the written description requirement. Univ. of California v. Eli Lilly, 43 USPQ 1396, 1406 (1997): "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." Again, this indicates that no exemplification is required once a generic structure is provided for a chemical invention.

Here, the genus is described by a generic structure that defines *by structure* the scope of the claimed compounds; from that, a person of ordinary skill *according to the Federal Circuit* would recognize "many of the species that the claims encompass," so it is "an adequate

description of the claimed genus.” Id. That structure satisfies the written description requirement based on the Federal Circuit’s express standards. This written description rejection is inconsistent with controlling precedent and should be withdrawn.

In addition, the specification provides reaction schemes A-G that depict general routes to introduce one group on the ring nitrogen and a different group on the 3-amino group nitrogen. Scheme C depicts the preparation of a compound wherein one of the members of the linking group L¹ is not carbon. These routes utilize well-known amide bond formation reactions and differential protection of the two nitrogen atoms, which would enable a person of ordinary skill to introduce a wide variety of groups for both L¹ and L². These routes further demonstrate that the person of ordinary skill would have understood the applicant to be in possession of the full scope of the invention as claimed. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 381092001600. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 15, 2007

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